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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/647,331	01/30/01	DICKINSON	P CARP-0085

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EXAMINER

OSTRUP, C

ART UNIT	PAPER NUMBER
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1619

DATE MAILED: 06/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Applicati n No.

09/647,331

Applicant(s)

DICKINSON ET AL.

Examiner

Clinton Ostrup

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 6-23, 25-33, 34-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 24 and 33 is/are rejected.
- 7) ☒ Claim(s) 6-23, 25-32, 34-35 is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.

- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: ____.

Application/Control Number: 09/647,331
Art Unit: 1619

Page 2

DETAILED ACTION

Claims 1-13 are pending in this application.

Priority

Priority to PCT/GB99/01019, filed April 1, 1999, is acknowledged. Further, it is acknowledged that the instant application claims priority to United Kingdom application number 9807232.5, filed April 3, 1998.

Claim Objections

Claims 6-23, 25-32, and 34-35 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, claims 6-23, 25-32, and 34-35 have not been further treated on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 24, and 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Glaxo Group Limited **WO 96/19968**. Glaxo Group Limited **WO 96/19968** discloses a pharmaceutical aerosol formulation for the administration of medicaments by inhalation comprising, a particulate medicament, at least one sugar, and a fluorocarbon or hydrogen containing chlorofluorocarbon propellant. See: abstract and page 1, line 30 – page 2, line 1.

Glaxo Group Limited **WO 96/19968** describes the particulate medicament as having a diameter of less than 15 micrometers, preferably in the range of 1 to 10 micrometers, thus meeting the size limitations of claims 1, 5, 24, and 33. See: page 2, lines 10-20. Glaxo Group Limited **WO 96/19968** further describe the sugar as having a particle size of less than 100, including sizes of 70 and 20 microns as examples of particle sizes under 100 microns, which meets the specific limitations of claims 1, 2, 24, and 33. See: page 4, lines 17-25. Glaxo Group Limited **WO 96/19968** also describe the ratio of medicament to sugar as being between the range of 1:0.01 to 1:100, preferably 1:0.1 to 1:10, thus meeting the ranges as claimed instantly by claims 3-4. See: page 4, lines 11-16.

The Glaxo Group Limited **WO 96/19968** reference meets the limitations of instant claims 1-5, 24, and 33 and therefore, clearly anticipates the instant invention.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Glaxo Group Limited, **WO 95/24889** reference describes a pharmaceutical composition for administration of medicaments comprising microfine particles of medicament and at least one lactose pellet having a diameter of 10-1500 micrometers. See: abstract and page 2, lines 15-25. The **WO 95/24889** reference describes how medicaments, for administration into the lungs, should be of a controlled particle size in the range of 1 to 10 micrometers in diameter for maximum penetration. See: page 1, lines 20-29.

The **WO 95/24889** reference describes the lactose pellet as having a diameter of from about 10 to 1500 microns and this pellet comprising a plurality of microfine lactose particles. See: abstract. Microfine is defined by the reference as a size, which permits substantially all of the particles to be potentially available for inhalation into the lungs upon administration of the powder composition. See: page 2 lines 15-25. The **WO 95/24889**


Application/Control Number: 09/647,331
Art Unit: 1619

further describes how the invention may be conveniently filled into a container, such as a multidose inhaler. See: page 7, lines 8-22.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on M-F (8:30am-5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


DIANA DUDASH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Clinton Ostrup
Examiner
Art Unit 1619

June 3, 2001